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Garlic Oil
Summary Document
Registration Review: Initial Docket
March 2009
Case 4007

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Approved By:

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I. PRELIMINARY WORK PLAN

Introduction

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States must generally be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health (including occupational and non occupational exposures) or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health and the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review .

The Agency has begun to implement the Registration Review program pursuant to FIFRA Section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial public docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for registration review of garlic oil.

1. What is Garlic Oil?

Garlic is a vegetable that belongs to the Allium class of bulb-shaped plants, which also includes onions, chives, leeks, and scallions. Garlic oil is the volatile oil extracted from the bulb of the garlic plant or the entire plant. Garlic has long been used for flavoring in cooking and is unique because of its high sulfur content. It is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) (21 CFR 182.20) and garlic and garlic oil are also listed as active ingredients that are acceptable for inclusion in minimum risk pesticides by EPA in 40 CFR 152.25(f)(1).

The EPA first registered a product containing garlic oil in 1983. There are 11 products registered with the Agency containing garlic, garlic oil, and garlic powder. The labels for these products list the active ingredient as Garlic Oil, Garlic Juice, Garlic Water, or Garlic. The Agency considers all such variations

of garlic or garlic oil as falling under the PC Code 128827 and Registry Number 8000-78-0. Further references herein are to garlic oil or garlic. Of the 11 registered products containing garlic oil as an active ingredient, two products are registered as insect repellents for agricultural use. The remaining products are registered for use as animal and insect repellents. Two of the 11 products contain garlic oil as the only active ingredient. The other products contain additional minimal risk products such as capsaicin, and putrescent whole egg solids as active ingredients along with garlic. All products are water-based compounds with extract of garlic or garlic powder.

As a biochemical active ingredient, garlic oil is used as a repellent for the control of insects, mites, birds, deer, rabbits and squirrels and is registered for use on terrestrial food and feed such as vegetables, fruits nuts and grains. Garlic oil is also registered for use on terrestrial non-food crops such as ornamental plants and shrubs.

Table 1. Garlic Oil Chemical Identity

Common Name	Garlic, Garlic Oil, Garlic Juice, Garlic Water
Chemical Name	Extract of
IUPAC	N/A
Trade Names	N/A
Molecular Weight	Varies
PC Code	128827
CAS Registry Number	8000-78-0
Empirical Formula	N/A
Registration Review Case Number	4007
Chemical Structure	N/A
End-use product/EP	Allityn Insect Repellent, Aphid-Pruf, Scoot Deer & Rabbit Repellent, Deer-Off Deer Repellent Concentrate, Deer-Off Deer Repellent spray, WS-DOSPCON X02, WS-DOSP X03, Deer-Off RTU II, Deer-Off Concentrate II, Deer-Off RTU III, Deer-Off Concentrate III, Nutripel – 20, Scarecrow

Anticipated Risk Assessment and Data Needs

Product Chemistry Assessment Status

The Agency has conducted a preliminary chemistry assessment of available product chemistry data and information associated with garlic oil as a repellent and its biochemical products in support of this registration review of garlic. Based on that review, the Agency has determined that there is adequate information available on garlic and therefore does not foresee the need to require additional generic product chemistry data.

Product Chemistry Summary

The Agency has conducted a review of the available product chemistry data and information. These data are summarized below.

Table 2. Product Chemistry Data Requirements Summary

Guideline No.	Physical and Chemical Properties	Status [1]	Value
830.1100	Product Identity and Composition	A	Refer to Table 1.
830.1200	Description of starting materials, production and formulation process	A	CBI
830.1400	Discussion of formation of impurities	A	CBI
830.1700	Preliminary analysis	A	CBI (EP)
830.6302	Color	A	Light tan to dark green
830.6303	Physical state	A	Liquid or powder
830.6304	Odor	A	Strong Garlic
830.6313	Stability to normal and elevated temperatures, metals and metal ions	A	Stable
830.7000	pH	A	5.5-6.0
830.7220	Boiling point/boiling range	N/A	Testing done on EP
830.7300	Density	N/A	Testing done on EP
830.7520	Particle size, fiber length, and diameter distribution	N/A	Testing done on EP
830.7550 830.7560 830.7570	Partition coefficient (n-Octanol/Water)	N/A	Partially soluble in water
830.7840	Water solubility	N/A	Testing done on EP
830.7950	Vapor pressure	A	10 Mm @ 20°C

1. **A=Acceptable, N/A=Not Applicable, N/D=Not Determined**

Human Risk Assessment Status

A preliminary human risk assessment has been conducted as part of the registration review of garlic oil. The agency has determined that, based on the available data and information for garlic, no new data or a new human health risk assessment are needed for garlic at this time. Hazard and exposure information as well as the Agency's risk assessments garlic oil on were evaluated against current safety standards and it has been determined that there is no need to conduct an additional human health risk assessment. Garlic is a naturally occurring substance, has a non-toxic mode of action and there is a significant history of exposure to humans and the environment. Further, there have been no

reports of adverse incidents for use of products containing garlic oil as an active ingredient. As such, the Agency believes that there is reasonable certainty that no harm will result to the general population from exposure to in products containing when the products are used according to label instructions.

Ecotoxicity Assessment Status

The Agency has also conducted a preliminary ecotoxicity assessment of garlic oil. Based on available information, the Agency does not foresee the need for additional ecotoxicity data. EPA has waived all hazard and exposure data on garlic oil. The unique characteristics of garlic oil, its non-toxic mode of action, and biodegradability (low to no persistence) should minimize the risks to all non-targets, including threatened and endangered species.

Endangered Species Assessment Status

The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether garlic's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

Anticipated Risk Assessment and Data Needs

None

Adverse Exposure Incidents

The National Pesticides Information Center (NPIC) database shows no human or ecological incidences related to garlic oil.

Guidance for Commenters

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan for the garlic oil case.

Stakeholders are also specifically asked to provide available information and data in the following areas:

- Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.
- Monitoring
- Structure Activity Relationships
- Toxicological Incidents
- Developmental Toxicity
- Environmental Toxicity

Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, because of their location, cultural practices, or other factors, may have atypical, unusually high exposure to Garlic compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

Water Quality

Garlic is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at: http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. The Agency invites submission of any other existing water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the"OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process (see:http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm), in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Trade Irritants

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. In the case of garlic oil, there are currently registered food uses and garlic oil is exempt from requiring a food tolerance. Additionally, there is no MRL established for garlic oil. Therefore, the Agency does not anticipate current uses of garlic oil to pose concerns as a trade irritant.

Structure Activity Relationships

EPA must rely upon information of appropriate quality and reliability for each decision made by the Agency. In the Office of Pesticide Programs (OPP), the evaluation process for a pesticide chemical traditionally begins with the applicant's submission of a set of studies conducted with the specific pesticide chemical of interest. The use of the results of such testing (measured data) is a logical, scientifically rigorous process that identifies the physical, chemical, and environmental fate properties of the pesticide, as well as the dose and endpoints at which an adverse effect can occur in various animal species.

Today, there is significant interest in alternative techniques, i.e., techniques other than data generation that could significantly inform the Agency's decision-making process. Recently, OPP has made increasing use of structure activity relationship (SAR) as part of its regulatory decision-making process. In the SAR process, a chemical's molecular structure is compared to that of other chemicals for which data are available. These structural similarities are then used to make predictive judgments about a chemical's physical, chemical, and biological properties. Thus, the chemical's physical, chemical, and biological properties are a function of (or directly related to) the chemical's molecular structure. Quantitative SAR is referred to as QSAR. To develop a QSAR, a selected set of measured data on a single physical, chemical, or biological property is used to derive a model (an equation) to predict the value of that property.

Since SAR assessments and QSAR modeling are another set of tools that are available to Agency scientists, OPP has begun a process shift that envisions shifting from the current study-by-study approach to an approach in which the use of predicted data, generated using validated models, is considered along with information from open literature and studies specifically generated under Part 158 requirements. All relevant information would be considered as part of a weight-of-the-evidence evaluation.

At this time, EPA believes that for certain endpoints, especially physical/chemical and fate properties, that SAR and QSAR might be effectively utilized to fulfill these data requirements for many antimicrobial pesticide chemicals. When considering biological properties, at this time, EPA believes that SAR and QSAR can be most effectively utilized in the evaluation of chemicals that exhibit lower toxicity for human health and/or ecotoxicity parameters. This is appropriate because the risk assessment for lower toxicity chemicals can be stream-lined, i.e., a screening-level assessment procedure rather than multiple tiers of assessments with progressively more data requirements.

If stakeholders believe that submission of predicted data can fulfill one of the data needs for garlic oil then the Agency invites submission of this information. The submitter would be expected to supply a rationale describing the utility of the information and provide documentation on the scientific validity of the information. The determination that the predicted data fulfills the data requirement would be at the sole discretion of the Agency. Pre-submission consultation with the Agency is encouraged.

TimeLine

EPA has created the following estimated timeline for completion of the garlic registration review case. This schedule is subject to revision should there be a need for a Data Call-In during the registration review process or should other issues arise.

Table 3. Timeline and Estimated Timelines

Activities	Estimated Month/Year
Open Public Comment Period for Garlic Docket	March 2009
Close Public Comment Period	May 2009
Phase 2: Case Development	
Develop Final Work Plan (FWP)	September 2009
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	February 2010
Close Public Comment Period	April 2010
Final Decision and Begin Post-Decision Follow-up	October 2010
Estimated Total (years)	1 year 7 months

Next Steps

After the 60-day comment period closes, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan for this registration review Case.

II. Garlic oil FACTSHEET (March 2009)

Garlic Oil Related Background Information

- Registration Review case number: 4007
- PC Code: 128827
- CAS#: 8000-78-0
- Source material
- Empirical Formula: NA
- Other Chemical Names: Garlic, garlic oil, garlic powder, garlic juice, garlic water,
- Original registrant – Helena Chemical Company
- Registration eligibility document published June 1992
- First approved for use in a registered product in 1983.
- Garlic oil is cleared as an acceptable active ingredient in minimum risk pesticides under 40 CFR 152.25(f).
- Biopesticide and Pollution Prevention Registration Review Lead: Cheryl Greene 703 308-0352 or greene.cheryl@epa.gov

Description of Active ingredient

Garlic oil, formulated as a powder or a distilled extract from garlic cloves, is an active ingredient in eleven registered pesticide products; most of these products also contain the active ingredient capsaicin (red pepper) and whole egg solids. The garlic pesticides are applied aerially or by ground equipment, and are used to repel deer, rabbits, squirrels, birds and/or insects. Once the garlic product adheres to plants the targeted pests are repelled by the taste and smell of the garlic and thus are prevented from damaging seeds and seedlings of vegetable plants, fruit trees, grain crops, ornamental plants and shrubbery.

EPA previously considered garlic to be a conventional chemical pesticide. However, the Agency has now reconsidered garlic as a biochemical pesticide because it is a naturally-occurring substance and has a non-toxic mode of action.

While EPA has developed a set of data requirements for registration, the Agency believes there is a category of pesticides for which a greatly reduced set of data requirements is appropriate. Such pesticides may be exempt from the usual generic data requirements for toxicology, residue chemistry, human exposure, ecological effects and environmental fate, without compromising human health or environmental safety. However, some data requirements (such as basic product identity and product chemistry data and acute toxicology studies) usually are essential, and generally will not be waived.

Garlic oil is in this category of pesticides. The bulb of a plant, its primary use in the United States is non-pesticidal; it is used widely to flavor and season foods. Garlic is

"generally recognized as safe," or GRAS, as a natural seasoning or flavoring (see 21 CFR 182.10, 182.20 and 184.1317).

Used as a pesticide, garlic has a non-toxic mode of action for repelling target birds and insects. Garlic is presumed to be non-persistent since it is material known to rapidly degrade in the environment. EPA has received no reports of adverse effects resulting from its use. The Agency believes that no significant adverse effect to humans or the environment is associated with the use of garlic as a pesticide.

Use and Usage

Garlic Oil Use information

- Garlic oil is used as a repellent for the control of insects, mites, birds, deer, rabbits and squirrels.
- Garlic oil is registered for use on terrestrial food and feed such as vegetables, fruits, nuts, and grains.
- Garlic oil is registered for use on terrestrial non-food crops such as ornamental plants and shrubs.
- Garlic oil is applied by aerial spray and hand spray application

Mode of Action – Garlic oil when used as a biochemical pesticide repels target organisms via taste and odor.

Use data since 2003 – The amounts used are tallied in gallons of garlicextract (garlic oil or garlic powder) and units sold, per Table 4 below)

Table 4. Use Data for Garlic Oil Measured by amount of Active Ingredient Sold

Year	Gallons Sold	Units Sold
2003	> 500,000	> 500,000
2004	> 40,000	> 40,000
2005	> 60,000	> 60,000
2006	> 120,000	> 120,000
2007	> 120,000	> 120,000

Recent Actions

There have been no recent significant regulatory activities regarding garlic products (i.e., tolerance related actions, changes of use patterns, submission of toxicological studies or incident reports.

Labels and Product Information:

The following table (Table 5) lists active and pending registrations of products containing (garlic as an active ingredient. Additional Labels and product specific information for the following products can be obtained from the Pesticide Product Label System (PPLS) website: http://oaspub.epa.gov/pestlabl/ppls.home.

Table 5: List of Pending and Active registrations for Garlic oil

Registration #	Registration Name	Company #	Company Name	Current Status	% of Active Ingredient
5905-531	ALLITYN INSECT REPELLENT	5905	HELENA CHEMICAL CO	Active - Conditionally Registered (08-Dec-1998)	50
44688-1	APHID-PRUF	44688	KITTENMOSELEY FERTILIZER & SUPPLY INC	Active - Conditionally Registered (05-Jun-2000)	10.8
65615-7	SCOOT DEER & RABBIT REPELLENT	65615	BALK FAMILY TRUST	Active - Registered (18-Apr-2008)	.12
67356-1	DEER-OFF DEER REPELLANT CONCENTRATE	67356	WOODSTREAM CORPORATION	Active - Conditionally Registered (27-Apr-1995)	.005
67356-2	DEER-OFF DEER REPELLENT SPRAY	67356	WOODSTREAM CORPORATION	Active - Conditionally Registered (23-May-1995)	.0006
67356-3	WS-DOSPCON X02	67356	WOODSTREAM CORPORATION	Active - Registered (28-Dec-2005)	.05
67356-4	WS-DOSP X03	67356	WOODSTREAM CORPORATION	Active - Registered (28-Dec-2005)	.0063
67356-5	DEER-OFF RTU II	67356	WOODSTREAM CORPORATION	Active - Registered (28-Dec-2005)	.0063
67356-6	DEER-OFF CONCENTRATE II	67356	WOODSTREAM CORPORATION	Active - Registered (28-Dec-2005)	.05
67356-7	DEER OFF RTU III	67356	WOODSTREAM CORPORATION	Active - Conditionally Registered (12-Sep-2008)	.001
67356-8	DEER OFF CONCENTRATE III	67356	WOODSTREAM CORPORATION	Active - Conditionally	.007

Registration #	Registration Name	Company #	Company Name	Current Status	% of Active Ingredient
				Registered (12-Sep-2008)	

Total Rows: 11

III. GLOSSARY of TERMS & ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
ASTM	American Society for Testing and Materials
AWPA	American Wood Preserver's Association
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that ccan be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAIRA	Pure Active Ingredient Radiolabelled

PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24(c)) of FIFRA)
TGAI	Technical Grade Active Ingredient
TEP	Typical End-Use Product
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard

IV. Bibliography

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